Clinical Policy Title:	sotorasib
Policy Number:	RxA.695
Drug(s) Applied:	Lumakras®
Original Policy Date:	8/18/2021
Last Review Date:	8/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Non-small cell lung cancer (must meet all):

1. Diagnosis of locally advanced or metastatic non-small cell lung cancer;
2. Member has KRAS G12C–mutated NSCLC as determined by an FDA-approved test;
3. Member has received at least one prior systemic therapy, unless clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 6 months

B. Pancreatic Adenocarcinoma (Off-label) (must meet all):

1. Diagnosis of locally advanced or metastatic pancreatic adenocarcinoma;
2. Disease is positive for KRAS G12C mutation.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indication in Section I (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Non-small cell lung cancer. Version 8.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed August 28, 20242. John H. Strickler, Hironaga Satake, Thomas J. George et.al. Sotorasib in KRAS p.G12C–Mutated Advanced Pancreatic Cancer. N Engl J Med 2023; 388:33-43. Available at: https://www.nejm.org/doi/full/10.1056/NEJMoa2208470#:~:text=Mutations%20in%20the%20Kirsten%20rat%20sarcoma%20viral%20oncogene,molecule%20that%20specifically%20and%20irreversibly%20inhibits%20KRAS%20G12C. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	8/18/2021	09/14/2021
Policy was reviewed: 1. References were reviewed and updated.	4/21/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, Pancreatic Adenocarcinoma (Off-label). 2. Continued Therapy Approval criteria, II.B: Updated to include approval criteria for indication, Pancreatic Adenocarcinoma (Off-label). 3. References were reviewed and updated.	05/29/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. Reauthorization criteria for all the diagnosis merged under “All Indications in Section I”. 8. References were reviewed and updated.	8/28/2024	9/13/2024